

## REMARKS

Reconsideration of the application in view of the following remarks is respectfully requested.

### I. Status of the Claims

Claims 17-30 are pending in this application. Claims 27-29 have been withdrawn from consideration. In the final Office Action mailed on August 27, 2008, claims 17-26 and 30 were rejected under 35 U.S.C. § 103.

### II. Rejections Under 35 U.S.C. § 103

The Examiner rejected claims 17, 18, 20-22, 24 25 and 30 under 35 U.S.C. § 103 as being unpatentable over United States Patent No. 5,660,170 to Rajan et al. in view of United States Patent No. 4,444,201 to Itoh. The Examiner rejected claims 19 and 26 under 35 U.S.C. § 103 as being unpatentable over Rajan in view of Itoh and further in view of United States Patent No. 5,551,419 to Froechlich et al. The Examiner rejected claim 23 under 35 U.S.C. § 103 as being unpatentable over Rajan in view of Itoh and further in view of United States Patent No. 5,868,133 to Devries et al.

Claim 17 recites an apparatus for providing pressure support to a subject that includes “controlling means for determining an average intrinsic positive end-expiratory pressure over a plurality of breathing cycles based on an output of the monitoring means, and for controlling the gas flow generating system such that a pressure of the flow of gas delivered to the subject during at least a portion of an expiratory phase of a breathing cycle substantially corresponds to the average intrinsic positive end-expiratory pressure.” Similarly, claim 30 recites a method for relieving dyspnoea in a subject that includes “determining an intrinsic positive end-expiratory pressure of the subject over a plurality of breathing cycles” and “controlling the pressure of the flow of gas delivered to the subject during an expiratory phase of a breathing cycle such that the pressure of the flow of gas substantially corresponds to an average intrinsic positive end-expiratory pressure.”

Rajan relates to determining an optimal “opening pressure” for a patient, which is a pressure at which the alveoli begin to open. The purpose for and significance of that determination is so that the lung system in Rajan can provide the determined opening pressure to

the patient during exhalation to ensure that the patient receives a pressure sufficient to open the alveoli. The opening of the alveoli in this manner allows for the efficient and proper gas exchange during the provision of therapy. Rajan describes a relatively elaborate technique for determining the opening pressure. That technique is not, however, based on a calculated average positive end-expiratory pressure (PEEP). It is thus clear that Rajan discloses neither “determining an average intrinsic positive end-expiratory pressure over a plurality of breathing cycles based on an output of the monitoring means” nor “controlling the gas flow generating system such that a pressure of the flow of gas delivered to the subject during at least a portion of an expiratory phase of a breathing cycle substantially corresponds to the average intrinsic positive end-expiratory pressure” as recited in claim 17. It is also clear that Rajan discloses neither “determining an intrinsic positive end-expiratory pressure of the subject over a plurality of breathing cycles” nor “controlling the pressure of the flow of gas delivered to the subject during an expiratory phase of a breathing cycle such that the pressure of the flow of gas substantially corresponds to an average intrinsic positive end-expiratory pressure” as recited in claim 30. As noted above, in Rajan, the optimal opening pressure (not based on average PEEP) is determined and that optimal opening pressure is provided to the patient during the expiratory phase in order to open the alveoli. The Examiner has acknowledged that Rajan “is silent with regards to averaging the PEEP.” The Examiner states, however, that Itoh discloses determining average PEEP and that it therefore would have been obvious to modify Rajan to determine an average PEEP (and presumably also then provide a pressure that substantially corresponds to the average PEEP to the patient during the expiratory phase as required in the claims). The Applicant strongly disagrees.

Itoh describes a respiration monitoring apparatus that includes a signal processing circuit which detects the end of the respective expiratory periods based on output signals from included meters (which denote the flow rate of breathed air flow) and stores the average value of the airway pressures determined at the end of the respective expiratory periods. In addition, when the measured airway pressure falls below the stored average value, the apparatus issues a detection signal denoting this condition and changes a display pattern on the monitor of the apparatus. Itoh does not disclose providing a pressure that substantially corresponds to the average PEEP to the patient, as the average PEEP level is used only for detecting an alarm condition for notifying the patient.

It is well settled that if a modification proposed by an examiner would render the prior art device being modified unsatisfactory for its intended purpose, then the proposed modification is not proper. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)<sup>1</sup>; MPEP §2143.01 V. Furthermore, as stated recently by the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, 127 S.Ct. 1727 (2007), in determining whether a proposed claim would have been obvious under 35 U.S.C. § 103 “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” Here, there is clearly no reason that would have prompted a person of ordinary skill in the relevant field to modify the system of Rajan to determine an average PEEP (*as opposed to an optimal opening pressure*) and then provide a pressure that substantially corresponds to the average PEEP (*as opposed to an optimal opening pressure*) to the patient during the expiratory phase as required in the claims. The *whole purpose and entire focus* of Rajan is to determine the optimal opening pressure of the patient so that the lung system in Rajan can then provide the determined optimal opening pressure to the patient during exhalation to ensure that the patient receives a pressure sufficient to open the alveoli. Thus, the modification proposed by the Examiner would clearly make Rajan unfit and inoperable for its intended purpose (which is to determine and provide an optimal opening pressure to the patient) as the optimal opening pressure would no longer be determined and provided to the patient. Furthermore, Itoh merely describes the determination of an average PEEP for purposes of alarm detection. Thus, for the reasons stated above, the Applicant submits that claims 17 and 30 would not have been obvious over Rajan in view of Itoh and requests that the rejection under 35

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<sup>1</sup> In *In re Gordon*, the claimed device was a blood filter assembly for use during medical procedures wherein both the inlet and outlet for the blood were located at the bottom end of the filter assembly, and wherein a gas vent was present at the top of the filter assembly. The prior art reference taught a liquid strainer for removing dirt and water from gasoline and other light oils wherein the inlet and outlet were at the top of the device, and wherein a pet-cock (stopcock) was located at the bottom of the device for periodically removing the collected dirt and water. The reference further taught that the separation is assisted by gravity. The Board concluded the claims were *prima facie* obvious, reasoning that it would have been obvious to turn the reference device upside down. The Federal Circuit reversed, finding that if the prior art device was turned upside down it would be *inoperable for its intended purpose* because the gasoline to be filtered would be trapped at the top, the water and heavier oils sought to be separated would flow out of the outlet instead of the purified gasoline, and the screen would become clogged.

U.S.C. § 103 be withdrawn. In addition, because claims 18-26 depend, directly or indirectly, from claim 17, they are likewise believed to be allowable.

Because the Applicant believes that claims 18-26 are clearly allowable due to their dependence on claim 17, the Applicant will not address the separate rejections of those claims under 35 U.S.C. § 103, but expressly reserves the right to do so in the future should the need arise.

### **CONCLUSION**

Based on the foregoing remarks, the Applicant respectfully submits that claims 17-26 and 30 are clearly in condition for allowance.

If a telephone conference would facilitate prosecution of this application in any way, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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